CGS
Jurisdiction B
P.O. BOX 20007
Nashville, TN 37202

MEDICARE DME

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

July 27, 2020

NOVOCURE INC
195 COMMERCE WAY
PORTSMOUTH, NH 03801

CONTACT INFORMATION

If you have questions, write or call:
Beneficiary Contact: 1-800-MEDICARE

CGS Administrators LLC
P.O. Box 20007
Nashville, TN 37202
1-866-590-6727

Beneficiary Name: Anniken Prosser
Medicare Number: XXXXXXXQM75
Claim Control Number: 20077805140000, 20108801847000 and 20140807927000
Appeal Number: 20181000889

Dear NOVOCURE INC:

This letter is to inform you of the decision on your Medicare Appeal. An appeal is a new and independent review of a claim. You are receiving this letter because an appeal was requested for the electrical stimulation device (E0766).

The appeal decision is unfavorable. Our decision is that your claims are not covered by Medicare. The supplier is responsible for payment.

More information on the decision is provided below. If you disagree with this decision, you may request a reconsideration to the Qualified Independent Contractor (QIC), Maximus Federal Services, Inc. You must file your appeal, in writing, within 180 days of receiving this letter. However, if you do not wish to appeal this decision, you are not required to take any action. For more information on how to request a reconsideration, see the section of this letter entitled, Future Appeal Rights.

A copy of this letter was also sent to Anniken Prosser.

CGS Administrators, LLC was contracted by Medicare to review your appeal.

SUMMARY OF FACTS

Provider	Dates of Service	Type of Service
NOVOCURE INC	March 16, 2020, April 16, 2020 and May 16, 2020	electrical stimulation device (E0766)

- Claims were submitted for E0766.
- An initial determination on these claims was made on March 24, 2020.
- The claims denied due to the following.
  • These are non-covered services because this is not deemed a "medical necessity" by the payer. This item or service does not meet the criteria for the category under which it was billed.
- On June 29, 2020, we received a request for a redetermination.
- The following documents are contained in the redetermination request case file: Delivery Ticket, Progress Notes and Doctor's Orders.

DECISION

We have determined that the above mentioned claims are not covered by Medicare. We have also determined that the beneficiary is not responsible for payment. Additionally, the submitted documentation has been reviewed by a Licensed Practical Nurse (LPN).

EXPLANATION OF THE DECISION

We reviewed the submitted documentation and information included in the case file. The Local Coverage Determination (LCD) L34823- Tumor Treatment Field Therapy (TTFT) states: Tumor treatment field therapy (E0766) is covered for the treatment of newly diagnosed Glioblastoma Multiforme (GBM) only when all of the following criteria are met:

1. The beneficiary has histologically confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, supratentorial GBM; and,
2. The beneficiary has received initial treatment with maximal debulking surgery (when feasible), followed by chemotherapy and radiotherapy; and,
3. Tumor treatment field therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy, whichever is later; and,
4. The beneficiary has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria; and,
5. The beneficiary has a Karnofsky Performance Score (KPS) of at least 70; and,
6. The beneficiary will use TTFT for an average of 18 hours per day.

If all of the coverage criteria above are not met, claims for code E0766 will be denied as not reasonable and necessary.

CONTINUED COVERAGE FOR NEWLY DIAGNOSED GBM BEYOND THE FIRST THREE MONTHS OF THERAPY:

Continued coverage of TTFT (E0766) beyond the first three months of therapy requires that no sooner than the 60th day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is continuing to use and is benefiting from TTFT.

Documentation of clinical benefit is demonstrated by:

1. In-person clinical re-evaluation by the treating practitioner; and,

2. Objective evidence of adherence to therapy, reviewed by the treating practitioner.

Adherence to therapy is defined as the use of TTFT for an average of 18 hours per day (excluding days the treating practitioner has documented a medical need to limit or interrupt treatment).

If the above criteria are not met, continued coverage of TTFT will be denied as not reasonable and necessary.

If the practitioner re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the beneficiary is benefiting from TTFT as defined in criteria 1 and 2 above, continued coverage of TTFT will commence with the date of that re-evaluation. See Policy Specific Documentation Requirements in the LCD-related Policy Article, located in the Related Local Coverage Documents section of this LCD, for information about KX modifier use.

RECURRENT GBM
Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary for the treatment of recurrent GBM.

OTHER USES
The use of TTFT for any indications other than newly diagnosed GBM will be denied as not reasonable and necessary.

BENEFICIARIES ENTERING MEDICARE
For beneficiaries who are undergoing treatment with TTFT for newly diagnosed, supratentorial GBM prior to enrollment in Fee-For-Service (FFS) Medicare and are seeking Medicare coverage of TTFT, coverage will be provided if all of the following coverage requirements are met:

a. The beneficiary has been receiving TTFT following initial maximal debulking surgery (if feasible) followed by chemotherapy/radiotherapy for histologically confirmed newly diagnosed GBM; and,
b. Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have an in-person evaluation by their treating practitioner who documents in the beneficiary's medical record that:
    1. The beneficiary is adherent with the use of TTFT for an average of 18 hours per day; and,
    2. The beneficiary is deriving benefit from the therapy.

If all of the above are not met, the claim will be denied as not reasonable and necessary.

The above guidelines were not met due to the following:

- The documentation provided does not show the coverage criteria above has been met.

We reviewed the submitted documentation and information included in the case file. The DME MAC Jurisdiction B Supplier Manual Chapters 3-Supplier Documentation, Section 4-Documentation in the Beneficiary's Medical Records and 16-Coding, Section 4-Modifiers state:

For any Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) item to be covered by Medicare, the beneficiary's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the beneficiary's diagnosis and other pertinent information including, but not limited to, duration of the beneficiary's condition, clinical course (worsening or improving), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. If the information in the beneficiary's medical record does not adequately support the medical necessity for the item, you are liable for the dollar amount involved unless a properly executed Advance Beneficiary Notice (ABN) of possible denial has been obtained.

The use of the KX modifier indicates that the requirements for the service or item billed have been met.

The above guidelines were not met due to the following:

- The claims were billed without a KX modifier.

Due to the Medicare guidelines that were not met, as discussed above, a favorable decision cannot be made.

WHO IS RESPONSIBLE FOR THE BILL

After determining that the item or service will not be covered by Medicare, we must determine who is financially liable for the denied item or service. When an item or service is denied under §1862(a)(1), §1862(a)(9), or §1879(g) of the Social Security Act (the Act), we must determine if the beneficiary and the provider or supplier either knew or could reasonably be expected to know that the item or service would not be covered. This is known as the limitation on liability provision of §1879 of the Act.

If the beneficiary was informed by their provider or supplier in writing in advance of receiving the items that Medicare may not make payment (through receipt of an Advance Beneficiary Notice of Noncoverage (ABN)), the beneficiary may be responsible for the cost of the denied item or service. If the provider or supplier knew or could reasonably be expected to know the item or service would not be covered, but the beneficiary did not have such knowledge, then the provider or supplier may be responsible for the cost of the denied item or service.

In addition, we have determined that the supplier either knew or could reasonably be expected to know that the items would not be covered. After reviewing the claims, we have determined that the services were not reasonable and necessary. We have also determined the beneficiary could not have been expected to know these services were non-covered. Prior to furnishing this service you did not obtain a valid signed Advance Beneficiary Notice of Noncoverage notifying the beneficiary that Medicare may not pay. Based on the information contained in the Local Coverage Determination (LCD)-L34823-Tumor Treatment Field Therapy (TTFT), DME MAC Jurisdiction B Supplier Manual Chapter 3 – Supplier Documentation and DME MAC Jurisdiction B Supplier Manual Chapter 16 – Coding, you could have been expected to know these services were non-covered. Therefore, you are liable for full charges for the services.

You may not bill the beneficiary for the cost of the denied item or service, and must refund any monies collected from the beneficiary.

Beneficiaries who have incurred a charge for this service may be due a refund. In order to receive reimbursement, the beneficiary must submit the following to this office: (1) a copy of this notice, (2) the supplier's invoice, and (3) a receipt or other documents indicating the beneficiary has made payment.

FUTURE APPEALS RIGHTS

If you disagree with this decision, you must request a reconsideration, in writing, within 180 days of receiving this letter. Your reconsideration request must include a copy of this letter along with the beneficiary's name, Medicare number, item or service in question, date of service, name of person appealing, signature, and date of signature. You may request an appeal by using the form enclosed with this letter. A copy of the reconsideration request form is also located at www.cgsmedicare.com or at www. MedicareDMEappeals.com. Reconsideration requests must be mailed to:

Maximus Federal Services, Inc.
Medicare DME
3750 Monroe Avenue, Suite 777
Pittsford, NY 14534-1302

All evidence should be submitted with the reconsideration request. As explained in the Explanation of the Decision section above, your reconsideration request should include supporting documentation indicating that medical necessity is met and documentation to support the effectiveness of this device. All evidence must be presented before the reconsideration decision is issued. You will not be allowed to submit any new evidence to the Administrative Law Judge or the Medicare Appeals Council unless you can demonstrate good cause for not submitting the evidence to the QIC during the reconsideration process.

NOTE: You do not need to resubmit documentation that was submitted as part of the redetermination. This information will be forwarded to the QIC as part of the case file utilized in the reconsideration process.

If you need more information or have any questions, suppliers should contact our office at 1-866-590-6727; beneficiaries should call 1-800-Medicare (1-800-633-4227).

Sincerely,

CGS, DME MAC Jurisdiction B
Medicare Appeals Department

cc: Anniken Prosser

RECONSIDERATION REQUEST FORM **Redetermination Number:** 20181000889
Contractor #: 17013, CGS, DME MAC Jurisdiction B

Directions: If you wish to appeal this decision, please fill out the information below and mail this form to the address below. At a minimum, you must complete/include information for items 1, 2a, 6, 7, 11, & 12, but to help us serve you better, please include a copy of the redetermination notice with your request.

Maximus Federal Services, Inc.
Medicare DME
3750 Monroe Avenue, Suite 777
Pittsford, NY 14534-1302

1. Name of Beneficiary: _____
2a. Medicare Number: _____
2b. Claim Number (ICN/DCN, if available): _____
3. Provider/Supplier Name and Number (PTAN): _____
4. Person Appealing ☐ Beneficiary ☐ Provider ☐ Representative of Service
5. Address of the Person Appealing: _____
5a. Telephone Number of the Person Appealing: _____
5b. Email Address of the Person Appealing: _____
6. Item or service you wish to appeal: _____
7. Date of Service: From _____ To _____
8. Does this appeal involve an overpayment? ☐ Yes ☐ No

**Please include a copy of the demand letter with your request.*

9. Why do you disagree? Or what are your reasons for your appeal? (Attach additional pages, if necessary.) _____

_____

10. You may also include any supporting material to assist your appeal. Examples of supporting materials include:

☐ Medical Records ☐ Office Records/Progress Notes ☐ Copy of the Claim

☐ Treatment Plan ☐ Certificate of Medical Necessity

11. Printed Name of Person Appealing: _____
12. Date: _____

Contractor Number: 17013, CGS, DME MAC Jurisdiction B